Application No.: 09/914,544
Amendment RCE Submission Filed Under 37 CRF 1.114

Remarks / Arguments

Current amendments

New claim 21 has now been redrafted so as to clearly underline that the tablets according to the invention are obtained by direct compression of a dry mixture of constituents.

New claim 31 has been redrafted to expressly indicate that the step consisting in mixing the different constituents of the tablet before the direct compression is carried out in a dry state.

Support for these amendments is to be found in the whole text of the specification and in particular in the examples.

Claims 21-39 are rejected under 35 USC 103(a) as being unpatentable over Liu et al. (US 6,465,009) in view of Schmitz et al. (US 6,079,968) and Valentine et al. (US 4,684,534).

This rejection is respectfully traversed.

It is respectfully submitted that the combination of the Liu et al. patent with the Schmitz et al. and Valentine et al. patents would neither teach nor suggest the presently claimed matter.

As stated in the response to the previous Office Action, the Liu et al. patent does not teach nor suggest methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

Furthermore and most importantly, tablets according to Liu et al. are completely different from tablets according to the invention as underlined and explained in MR. GENDROT'S DECLARATION UNDER RULE 132 which is herewith enclosed.

Tablets according to Liu et al. are not obtained by direct compression of a dry mixture of constituents.

Tablets according to Liu et al. are obtained by a process including:

- wet granulation of a mixture including the active substance, and
- humidification and subsequent drying.

Said succession of wet granulation, humidification and drying steps result in a specific structure of the tablet which consists in a relatively soft interior and a relatively harder outer (exterior) surface layer as indicated at column 10, lines 15-18.

The structure of the tablets according to the invention is homogeneous due to the fact that it results from a direct compression of a dry mixture of constituents.

The structure of Liu's tablets is thus very different from that of the tablets according to the invention.

Furthermore, it is important to note that PVP (Kollidon) is different from cross-linked-PVP (crospovidone or Kollidon CL) (see herewith attached Enclosure A) . The former is a water-soluble binder whereas the latter is a water-insoluble disintegrant. Thus, example 7 of Liu, which is cited by the Examiner, lacks disintegrant and is thus different from tablets according to the invention.

In fact only cross-linked PVP i.e. crospovidone (Kollidon LP), which is water-insoluble, is considered as a disintegrant. And, when PVP is incorporated in tablets, it acts in a different way than cross-linked PVP.

As indicated in MR. GENDROT'S DECLARATION UNDER RULE 132, the disintegration of tablets according to Liu et al. is due to the dissolution of PVP in the presence of water.

However, in the presence of water, the tablets according to the invention explode due to the presence of the disintegrating agent which is not soluble.

As already indicated, there is no incentive to combine Liu et al. and Schmitz and even if the skilled artisan expressly applies the teachings from Schmitz et al. patent to the tablets described in Liu et al. patent, he will never obtain the tablets of the invention.

It results from the above that the present invention is non-obvious over the Liu et al. in view of the Schmitz et al. and Valentine patents.

It is thus respectfully requested that the above cited rejection be withdrawn.

In view of the above, it is respectfully submitted that the application is now in proper form for allowance.

Respectfully submitted,

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